

PSJ3
Exhibit 387

Message

From: Ducca, Anita [aducca@hdmanet.org]
Sent: 3/4/2008 7:02:33 PM
To: Ducca, Anita [aducca@hdmanet.org]
Subject: HDMA RAC Conference Call Reminder -- Mar. 6, 2008 2:00 - 4:00 pm EST
Attachments: Antitrust Policy - HDMA.doc; 03-06-08 RAC confcallagenda.doc; 2008-4336s1-05-Adolor-Jackson.pdf; HDMA Final DRAFT SO BPs Mar 4 08 .DOC

Dear RAC Members:

This is to remind you that our next Conference call will be this **Thursday, March 6th from 2:00 to 4:00 pm**. The HDMA Antitrust policy and the agenda and are attached. To join the call, please use the following:

Dial-in number: 1-800-531-3250

CONFERENCE ID NUMBER: 8594739

Also, please be reminded that the meeting with Mark Caverly will be held on May 6th. We'll go over plans for that meeting, including a time frame for the RAC to meet before and/or after Mark's time slot, and start to develop questions we would like Mark to cover at the meeting. I'm also forwarding the e-mail I sent out last week, since we'll be discussing these issues on Thursday as well.

Finally, I've attached a copy of the very latest version of the draft suspicious orders practices. The Executive Committee approved these, but indicated HDMA should continue to work with the Regulatory Affairs Committee and other relevant staff on the details. Also, we have made some changes, mostly regarding wording and formatting, and included recommendations by our Outside Counsel and our Communications Department including a suggestion to rename them to "Recommended Practice Guidelines." A few are substantive, so we'd like to review them one last time to make sure the changes don't change the meaning or create operational difficulties.

If you have any questions, please be sure to contact me. I look forward to our conference call this Thursday.

Anita

From: Ducca, Anita
Sent: Friday, February 29, 2008 3:19 PM
To: Ducca, Anita
Subject: HDMA - RAC - Important Information and Next Conference Call -- Mar. 6, 2:00 - 4:00 pm EST

Dear RAC Members:

I have several important items to share with you.

1. Our **next RAC conference call** will be **Thursday, March 6th from 2:00 to 4:00 pm EST**.

2. We have a date for the meeting with

Mark Caverly of DEA

Tuesday, May 6, 2008

HDMA's Offices - 901 North Glebe Road, Arlington, VA

Mark will also bring Cathy Gallagher, Associate Section Chief, and Loren Miller, Unit Chief of the Policy Unit. I'll send more details out before the meeting. *A list of hotels near to HDMA is attached below.* HDMA will not be reserving a block of rooms, but note that there is a corporate HDMA rate at the Westin. We suggest that you make reservations early -- they tend to get very booked up. If you have questions on the hotels, please contact my assistant, Pam Ritter.

As I mentioned in an earlier e-mail, we plan to keep this meeting relatively small and are suggesting that no more than two attendees per member company plan to attend. So that we can firm up our count, **please let me or Pam Ritter know of your plans to attend by Wednesday, March 13.** We're going to open it up to more than 2 per company if the numbers interested are relatively small. **(If you have already told us you plan to attend we do not need another e-mail)**

3. Yesterday, **DEA sent us an updated list of DEA registrants eligible to receive 40 mg Methadone products.** The HDMA Web site now contains the file. Please see the link at:

http://crm1.hdmanet.net/eweb/DynamicPage.aspx?webcode=sf_active_distparent&f=methadone.zip

You will need to use your HDMA username and password to access the link to view the list. Once you enter your HDMA username and password, you will get the option to open or save the resulting zip file. If you **have trouble entering your username or password, please contact Heidi Rohrbach** at hrohrbach@hdmanet.org or 703-885-0238 or **Luci Blodgett** at lblodgett@hdmanet.org or 703-885-0220.

In the future, DEA will be charging a fee for this information. Specifically, Johanna Clifford, Denise Curry's Special Assistant, stated: *"We are pleased to accommodate the request as your members update their systems to allow for changes that may be needed, however, for long term purposes, this information is available online and can be purchased for a fee."* Early next week, I will call Johanna to find out more about what that involves, how much, etc.

4. Issues regarding Risk Minimization Action Plans (RiskMaps), which for distributors means Restricted Distribution programs such as iPLEDGE or 40 mg Methadone, are likely to be resurfacing. FDA is looking into implementing FDAAA's RiskMap provisions and Suzanne Barone of FDA's enforcement office contacted me this week with a number of questions about impacts. I brought up:

- the heavy duty operational/IT issues with daily matching of qualified recipients,
- the problems with reporting on sales,
- the need for consistency among the programs, especially if multiple manufacturers each establish their own separate and different restricted distribution requirements.
- I also brought up the problem with the iPLEDGE program where one requirement was going to be reporting sales data, without charging an extra fee.

Also, Suzanne told me about an FDA Advisory Committee meeting in January, where a manufacturer (Adolor) proposed a restricted distribution program for a new drug they want FDA to approve (Entereg®). Adolor proposed that if approved, Entereg® **would be distributed only to acute care hospitals and the distributor would file daily tracking reports.** The attachment from that meeting describe Adolor's plans starting on slide 18.

The slides indicate that Adolor thinks this is not much of an imposition on distributors, but **I would like your feedback especially if anyone has had contact with the manufacturer on this.** We intend to include this issue on our call on March 6.

5. Finally, we plan to bring up DEA's implementation of 21 CFR 1301.93 which spells out what DEA recommends for employee checks, which includes "DEA Inquiries". 21 CFR 1301.76(a) requires registrants to not employ, as an agent or employee who has access to controlled substances, any person who has been convicted of a felony offense relating to controlled substances or who, at any time, had an application for registration with DEA denied, revoked or surrendered for cause.

The only way to determine this is if a records check is conducted by DEA. We've heard that DEA has been inconsistent in their interpretation of these regulations, with some offices agreeing to conduct these checks on any employee we request, others will only conduct checks on cage and vault employees, and some office have refused to conduct these checks at all. We'd like to discuss your experiences and whether HDMA should request clarification from DEA.

I'll be sending out a more complete agenda for our call next week. In the meantime, If you have any questions, please feel free to contact me.

Regards,

Anita

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